

REMARKS

I. Claim Status

This submission is in response to the non-final Office Action dated April 13, 2007. Applicants have amended claims 5, 7, 9, 11, and 13 to reflect the election of species from the response filed March 8, 2007. Support for these amendments is found in the original claims as filed. Claim 1 has been amended to include the limitations of claims 10 and 16. Support for these amendments is found in claims 10 and 16. Claim 2 has been amended to correct antecedent basis. Support for the amendment is found in original claim 2 as filed. Claim 17 has been amended to clarify the amount of the recited components. Support for this amendment is found in the specification on pages 48-49. Claims 18-30 stand withdrawn as non-elected claims. Accordingly, Applicants presently cancel claims 10, 14, 16, and 18-30. Therefore, claims 1-9, 11-13, 15, and 17 are currently pending.

No new matter is added by way of these amendments. Consideration of the above-identified application, in view of the following remarks, is respectfully requested.

II. Rejections Under 35 U.S.C. § 112, ¶2

Claim 2 stands rejected as lacking proper antecedent basis for the terms “the water-soluble, organic zinc salts”. Applicants have amended the claim per the Examiner’s suggestion. Therefore, applicants request the rejection be withdrawn.

Claim 17 stands rejected for use of the term “synergistic”. Applicants have amended the claim to clarify that the “synergistic amount” refers to an effective amount to have a synergistic effect against bacterial growth. Support for this amendment appears on pages 48-49 of the specification, and in Table 11. Accordingly, Applicants respectfully request the rejection be withdrawn.

III. Rejections Under 35 U.S.C. § 112, ¶1

Claim 16 stands rejected as failing to comply with the written description requirement. According to the Examiner, the recitation of “one more natural or synthetic chemicals” is not supported by the specification. Applicants have amended claim 16 to specifically recite

“farnesol” as a result of the species election. Therefore, the claim amendment renders the rejection moot. Applicants respectfully request that the rejection be withdrawn.

IV. Rejections Under 35 U.S.C. § 102(b)

Claims 1-5 stand rejected as anticipated over U.S. Patent No. 5,985,918 (to Modak et al. ('918 patent)). According to the Examiner, Modak teaches all elements of the claimed invention. Applicants traverse the rejection and respectfully request reconsideration.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants submit that claim 1, as amended, requires the presence of an antimicrobial at a concentration of between 0.05% - 4% (weight/weight), as well as the presence of the compound farnesol. As noted above, support for these amendments is found in claims 10 and 16. Modak ('918 patent) fails to teach all elements of the claimed invention. In particular, Modak ('918 patent) fails to teach the use of farnesol, let alone any essential oil, in any of the disclosed compositions. As such, Modak ('918 patent) can not anticipate the claimed invention. Accordingly, applicants respectfully request that the rejection be withdrawn.

V. Rejections Under 35 U.S.C. § 102(e)(2)

Claims 1-13 and 15-17 stand rejected as anticipated over U.S. Patent No. 6,344,218 (to Dodd). According to the Examiner, Dodd teaches all limitations of the pending claims. Applicants traverse the rejection and respectfully request reconsideration.

Applicants submit that in order for a reference to anticipate, the reference must disclose each and every limitation of the claimed invention, and must be an embodiment of the claimed invention. *Dana Corp. v. Am. Axle & Mfg., Inc.*, 61 USPQ2d 1609 (Fed. Cir. 2002) (emphasis added). The teaching must clearly disclose the invention with a certain degree of precision, without the need for picking and choosing components. *Ex parte Westphal*, 223 USPQ 630 (Bd. Pat. App. 1983). The Court of Customs and Patent Appeals has counseled against “the mechanistic dissection and recombination of the components of the specific illustrative compounds in every chemical reference containing them, to create hindsight anticipations with the guidance of an applicant’s disclosures, on the theory that such reconstructed disclosures

describe specific compounds within the meaning of section 102.” *In re Ruschig*, 343 F.2d 965, 974 (C.C.P.A. 1965).

Contrary to the Examiner’s assertion that Dodd discloses each and every element of the claimed invention, Applicants respectfully submit the Dodd fails to teach the claimed invention. As noted above, claim 1 has been amended to include the presence of an antimicrobial at a specific concentration, as well as farsenol. Specifically, Dodd fails to teach the use of farsenol, or broadly any essential oil, in the claimed invention. Furthermore, Dodd fails to teach the claimed embodiments of the inventions, but rather discloses various components (but not all) in list fashion, requiring one skilled in the art to pick and choose various elements to attempt to arrive at the claimed invention. Since Dodd fails to teach and/or disclose all elements of the claimed invention, Dodd can not anticipate the claimed invention. Accordingly, applicants request that the rejection be withdrawn.

VI. Rejections Under 35 U.S.C. § 103(a)

Claims 1-17 stand rejected as unpatentable under 35 U.S.C. § 103(a) over Modak (‘918 patent). According to the Examiner, Modak (‘918 patent) teaches all elements of the claimed composition. The Examiner alleges that Modak (‘918 patent) teaches the use of zinc compounds in various bases, thereby rendering obvious a formulation of two or more zinc salts as is presently claimed. The Examiner states that it is not inventive to discover optimum ranges, and erroneously concludes that the claimed ranges would have been *prima facie* obvious.

Claims 1-17 also stand rejected as unpatentable under 35 U.S.C. § 103(a) over Dodd. The Examiner asserts that Dodd discloses odor-controlling compositions comprising odor controlling agents, alcohol antiseptic, metallic salt, thickener, emollient, perfume, and water. According to the Examiner, one skilled in the art could arrive at the claimed optimum ranges through routine experimentation. The Examiner states that “it is not inventive to pick and choose specific excipients and specific concentrations from the Dodd et la. disclosure.” See Office Action, page 14.

Applicants respectfully traverse these rejections and request reconsideration.

Applicants respectfully submit that the present claims are not obvious over the cited art. First and foremost, contrary to the Examiner’s position, Modak (‘918 patent) and Dodd fail to teach all elements of the claimed invention. As noted previously the claimed invention requires

the presence of two or more zinc compounds, an antimicrobial, farsenol, water, ethanol, and one or more of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient. Not only do both references fail to teach all of these elements, one skilled in the art would have no specific motivation to add any missing components, such as, for example, farsenol.

Based on at least this reason, Applicants submit that a *prima facie* case of obviousness has not been established. However, assuming *arguendo*, that a *prima facie* case of obviousness has been established, which applicants do not concede, Applicants have provided unexpected results to rebut a *prima facie* case. According to the Manual of Patent Examining Procedure (MPEP), evidence of unobvious or unexpected advantageous properties rebuts *prima facie* obviousness. MPEP 716.02(a). The presence of a property not possessed by the prior art is sufficient evidence of nonobviousness. *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

Contrary to the Examiner's assertion that one skilled in the art could arrive at the claimed amounts of zinc, Applicants submit that based on the teachings of the present invention, the presently claimed invention clearly provides unobvious and unexpected results. As explained in the background of the present specification, systemic zinc toxicity through skin or mucosa may be a risk in using creams or gels containing high concentrations of water-soluble zinc salts. (See ¶ 17 of published application 2004/0102429A1). However, the present invention has found a way to balance an upper limit of zinc salts with the necessary concentration to achieve the desired effect of preventing irritation:

... specific combinations of two or more water-soluble organic salts of zinc have been identified that are effective in preventing irritation caused by spermicides, microbicides, and alcohol-based gels at concentrations that are low enough so that the risk of zinc toxicity, inactivation of therapeutic compounds, and mucosal irritation are minimized. The incorporation of zinc salt combinations into contraceptive or antiseptic lubricants or creams will thus render these products less irritating to the underlying mucosa, and therefore better able to protect against the contraction of infectious diseases, while maintaining the effectiveness of these products for their intended use.

(See ¶ 19 of published application 2004/0102429A1). The surprising aspect of the invention is the finding that low concentrations of zinc salts, as claimed, achieve anti-irritant effect while minimizing zinc-induced irritation and toxicity. Examples 1-3 and 7-9 in the present

specification demonstrate the benefits of zinc combinations over a single zinc compound. In Modak ('918 patent), Table A in the Examples, show that lower doses of zinc compounds result in itching and redness, which is contrary to the findings of the present invention.

Further, Example 4 of the present specification show that normally zinc salts interfere with spermidical effects, however the zinc compounds of the present invention have been formulated to allow the use of more than one zinc compound without impairing detergent activity (as measured by ability to lyse red blood cells). Additionally, Example 6 demonstrates a rapid and sustained effect with these specific low concentrations of zinc compounds. Lastly, the remaining Examples demonstrate the synergistic benefit of combining the low concentration zinc salts with additional components such as chlorhexidine gluconate and benzalkonium chloride. Clearly, Applicants have provided more than adequate disclosure of unexpected results with the use of low concentration zinc salts. Therefore, Applicants submit that the claimed invention is nonobvious over the cited art. Accordingly, Applicants request the rejection be withdrawn.

Claims 1-17 also stand rejected as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,183,766 (to Sine) in view of U.S. Patent No. 5,965,610 (to Modak ('610 patent)). According to the Examiner, Sine is directed to skin moisturizing compositions containing all elements of the invention. The Examiner states that Modak ('610 patent) discloses skin care compositions useful as anti-irritants, and thus concludes that it would have been obvious to formulate a skin care composition based on the contents of Sine. The Examiner concedes that Sine fails to recognize the anti-irritant of zinc salts, but states that the claimed invention would be attainable through routine experimentation. Applicants respectfully traverse this rejection and request reconsideration.

Applicants submit that a *prima facie* case of obviousness has not been established. As noted above, the present invention provides ample data regarding unexpected benefits with the use of multiple low concentration zinc salts. The Examiner glosses over the lack of Sine's recognition of the anti-irritant feature of zinc salts, however, this is contrary to what was known in the art. Rather, as discussed in the background of the invention, zinc compositions at higher concentrations pose the risk of toxicity and irritation. However, as shown in Modak ('918 patent), lower concentrations were not effective in preventing irritation.

Sine fails to teach the use of multiple zinc compounds at low concentrations for any anti-irritant effect. Reliance on Modak ('610 patent) fails to provide any further insight. Rather

Modak ('610 patent) is directed to higher concentrations of single zinc salts. The present invention has discovered that it is possible to lower the dose, while maintaining effectiveness, by using multiple zinc compounds in the formulation. This discovery is not apparent nor obvious based on the cited art. For at least the reasons provided herein, the claimed invention is not obvious over the Sine in view of Modak ('610 patent). Therefore, Applicants respectfully request that the rejection be withdrawn.

VII. Double Patenting

Claims 1-17 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 4-8, and 11-15 of U.S. Patent No. 5,965,610. Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants will agree to submit a terminal disclaimer at such necessary time.

Claims 1 and 3-17 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-3 of U.S. Patent No. 5,985,918. Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants will agree to submit a terminal disclaimer at such necessary time.

Claims 1-2 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 19-14 and 39-42 of copending application no. 10/892,034. Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants will agree to submit a terminal disclaimer at such necessary time.

VIII. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe no additional fee other than the three-month extension of time is due at this time. However, if any additional fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

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Respectfully submitted,
BAKER BOTTS L.L.P.



Lisa B. Kole
Patent Registration No.: 35,225
Attorney For Applicants

Sandra S. Lee
Patent Registration No.: 51,932
Attorney For Applicants

30 Rockefeller Plaza
44th Floor
New York, NY 10112-4498
(212) 408-2500
(212) 408-2501 (fax)